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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,670	07/08/2005	Volker Lipka	G1309 US S3	4986

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,670	LIPKA ET AL.	
	Examiner	Art Unit	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *9,10 and 17-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 11-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 September 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 10/11/07 is acknowledged. The traversal is on the ground(s) that that Groups I-VII are all so linked as to form a single general inventive concept because they all involve polypeptides with the amino acid sequence of SEQ ID NO: 2 and polynuclotides with the nucleotide sequence shown in SEQ ID NO: 1. Applicant argues that Lefebvre et al reference does not describe SEQ ID NO: 1 or SEQ ID NO: 2 and/or homologous sequences thereto. Applicant alleges that the Examiner has not set forth sufficient grounds to assert that Lefebvre describes Applicant's special technical feature. Applicant, therefore, requests, the election/restriction requirement be withdrawn.

Applicant's arguments have been fully considered but are not found persuasive because the invention of claim 1, part (c), recites a recombinant polynucleotide comprising a nucleotide sequence encoding a fragment (of any size) of SEQ ID NO: 2 or a fragment (of any size) of a polypeptide encoded SEQ ID NO: 1 having beta-glucosidase activity. In the Search Report provided by Applicant on 09/03/04, multiple prior art references were cited against Applicant's claim 1. Also, on page 56, Example 5, Applicant admits that the instant PEN2 shares 55.2% identity with a known Arabidopsis beta-glucosidase. The beta-glucosidase refore, the invention of claim 1 does not avoid the prior art. Applicant has provided no evidence that shows how such a fragment differs from the prior art beta-glucosidase. In addition, under PCT rule 37 CFR 1.475(d), where multiple products such as nucleic acids (first product), polypeptides

(second product), antibody (third product), and kit (fourth product) are claimed as in the instant application, Applicant is entitled unity of invention between first product and the method of using and the method of making the product. Therefore, the requirement is still deemed proper and is therefore made FINAL.

Claims 1-23 are pending.

Claims 9-10 and 17-23 are withdrawn from consideration as being directed to the non-elected invention.

Claims 1-8 and 11-16 are examined.

Sequence Listing

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and amino acid sequences set forth in 37 CFR1.821 (a)(1) and (a) (2). The CRF and paper sequence listing of 1/19/05 have been entered. However, the sequence listings do not comply the sequence rule 37 CFR 1.821(d) as shown in the attached Notice to Comply. The 37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. The sequences on Figs. 9 and 12 lack SEQ ID NO: Applicant is respectfully requested to identify the sequences on Figs. 9 and 12 or to submit a new Sequence Listing, which comprises said sequences.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The specification is objected to for missing the heading of sections (g), (h), and (i).

Copending Applications

Applicants must bring to the attention of the Examiner, or other Office official involved with the examination of a particular application, information within their

knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See *Dayco Products Inc. v. Total Containment Inc.*, 66 USPQ2d 1801 (CA FC 2003).

Specification

The disclosure is objected to because of the following informalities: for example, page 47, 4rth paragraph; and page 56, contains an embedded hyperlink directed to an Internet address. The use of hyperlinks and/or other form of browser- executable code are not permitted under USPTO current policy because the content of such links are subject to a change, resulting in the introduction of New Matter into the specification. Applicant is required to check the application for any embedded hyperlinks and/or other browser-executable code and delete it. See MPEP 608.01. The specification is also objected to for including blank spaces on page 47, 4rth paragraph. Appropriate correction is required.

Drawings

The drawings are objected to because the content of Figures 1-2 and 4 are either blurry or too dark and not legible. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be

removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

At claim 1, "polynucleotides" should be changed to --a polynucleotide-- for clarification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-7 and 12-16 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite because the polynucleotide defined in claim 1 lacks antecedent basis; claim 1 is directed to a recombinant nucleic acid molecule rather than to a polynucleotide. Dependent claim 4 is included in the rejection.

Claim 5 is indefinite because the polynucleotide defined in claim 1 lacks antecedent basis; claim 1 is directed to a recombinant nucleic acid molecule rather than to a polynucleotide.

Claim 5 is indefinite for lacking correlation between the preamble and the method step. The preamble reads producing host cells, and the method step requires introducing the recombinant nucleic acid of claim 1 into a host cell. Dependent claim 6 is included in the rejection.

Claim 8 is indefinite because "the cells" in the last line lacks antecedent basis. Claim 8 is indefinite because the polynucleotide defined in claim 1 lacks antecedent basis; claim 1 is directed to a recombinant nucleic acid molecule rather than to a polynucleotide.

Claim 11 is indefinite because the polynucleotide defined in claim 1 lacks antecedent basis; claim 1 is directed to a recombinant nucleic acid molecule rather than to a polynucleotide.

Claims 12 and 15 are indefinite because "the plant cells" of claim 7 lacks antecedent basis; claim 7 is drawn to a host cell, wherein the host cell is a plant cell.

Claims 13-14 and 16 are indefinite because the polynucleotide defined in claim 1 lacks antecedent basis; claim 1 is directed to a recombinant nucleic acid molecule rather than to a polynucleotide.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 11-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a recombinant nucleic acid molecule comprising SEQ ID NO: 1 or a polynucleotide encoding SEQ ID NO: 2, transgenic plant or host cell/yeast, bacteria/fungus comprising said recombinant nucleic acid molecule and a method of transforming a plant/host cell with said recombinant nucleic acid molecule, does not reasonably provide enablement for a recombinant nucleic acid molecule comprising a polynucleotide encoding a fragment of SEQ ID NO: 2 or encoding a polypeptide having at least 50% to SEQ ID NO: 2 and having beta-glucosidase activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a recombinant nucleic acid molecule comprising a polynucleotide comprising a nucleotide sequence encoding a fragment of SEQ ID NO:

2 or a fragment of the polypeptide encoded by SEQ ID NO: 1 having beta-glucosidase activity, or a polynucleotide which encodes a polypeptide having a sequence identity of at least 50% to SEQ ID NO: 2 or to a polypeptide encoded by SEQ ID NO: 1, wherein said polypeptide has beta-glucosidase activity; and a heterologous promoter operatively linked to said polynucleotide; a vector comprising said polynucleotide; a method of introducing said recombinant nucleic acid molecule or vector into said host cell/plant to produce polypeptide or to produce transgenic plant having pathogen resistance or transformed plant/host cell. In contrast, Applicant teaches isolation of a nucleic acid encoding SEQ ID NO: 2 and methods of using said nucleic acid to transform a host cell/plant.

Applicant has not taught the obtention and use of a nucleic acid encoding a polypeptide having at least 50% identity to SEQ ID NO: 2 and that retains beta glucosidase activity. Applicant has not disclosed a transgenic plant having resistance against a pathogen as a result of expressing exemplified or non-exemplified nucleic acids. Applicant has not taught which regions in SEQ ID NO: 1 or 2 that are essential for the beta glucosidase activity.

Applicant has not provided guidance for how to identify or obtain all nucleotide sequences having both the structural and functional limitations as recited in the claims. The breadth of the claims encompasses nucleotide sequences obtainable by modifications including multiple deletions and/or substitutions of amino acids in SEQ ID NO: 2. However, Applicant has not taught which regions in SEQ ID NO: 3 would tolerate such modifications. Therefore, Applicant has not provided guidance for modifications to

SEQ ID NO: 2 that resulted nucleotide sequences having both the structural and functional limitations as recited in claim 1, (parts c-d).

While mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claims. One skilled in the art would expect any tolerance to modification for a given DNA/protein to diminish with each further and additional modification or multiple substitutions/ deletions. One skilled in the art would have to make all possible nucleotide substitutions and deletions in the 1683 nucleotide long sequence of SEQ ID NO: 1 or in the 560 amino acid long sequence and test all sequences that meets the structural limitations to determine which also meet the functional limitation.

In addition, since the working example disclosed in the specification is limited to unmodified SEQ ID NO: 1, the ability of SEQ ID NO: 1 to encode a polypeptide having glucosidase activity and hence induce disease resistance cannot be extrapolated to any variant thereof, absent specific guidance.

Therefore, given the breadth of the claims, the nature of the invention, the unpredictability in the art with respect to DNA/protein modifications, the limited guidance and working examples in the specification as discussed supra, and the state of the prior art, the claimed invention is not enabled throughout the broad scope. See In re Wands 858 F.2d 731, 8USPQ2nd 1400 (Fed. Cir, 1988).

See, also, *Amgen Inc. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1027 (Fed. Cir. 1991) where the court held that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8 and 11-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Harper et al (US 7,109,033 B2).

The claims are drawn to a recombinant nucleic acid molecule comprising a polynucleotide encoding a fragment of SEQ ID NO: 2 or the polypeptide encoded by SEQ ID NO: 1, a polynucleotide which encodes a polypeptide having a sequence identity of at least 50% to SEQ ID NO: 2 or to a polypeptide encoded by SEQ ID NO: 1; said polypeptide has beta-glucosidase activity; said polynucleotide operably linked to regulatory sequences; a vector comprising said recombinant nucleic acid molecule; transgenic host cell/plant comprising said vector or nucleic acid molecule; and a method of introducing said recombinant nucleic acid molecule or vector into said host cell/plant

to produce polypeptide or to produce transgenic plant having pathogen resistance or transformed plant/host cell.

Harper teaches a recombinant nucleic acid/vector comprising a nucleotide sequence encoding a polypeptide that is 100% identical to Applicant's SEQ ID NO: 2 (see attached alignment of sequence) and having beta-glucosidase activity (see SEQ ID N: 54 on Table 1; column 61) operably linked to regulatory sequences including a promoter region; transgenic plant/cell and host cells transformed with said vector or recombinant nucleic acid; and a method of transforming host cell/plant with said vector to produce transgenic plant having resistance against stress (see at least col. 4-5; paragraph bridging 13-14; col. 19-20, 29-34, and 43-49). Since the nucleic acid of Harper (SEQ ID NO: 54) is 100% identical to Applicant's SEQ ID NO: 1, the disease resistance activity is an inherent property to the Harper's SEQ ID NO: 54. Therefore, Harper teaches all claim limitations.

Claims 1-8 and 11-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Duvick et al (US 6, 433,249 B1).

Duvick et al an isolated gene encoding a polypeptide having beta glucosidase activity that is cloned into a plant expression vector comprising regulatory sequences, and methods of transforming a host cell and plants with said vector to produce transgenic plants having enhanced resistance to diseases and insects. The cited reference also teaches transformed plants and host cells expressing said polypeptide having beta glucosidase activity. Given that claim 1, part c encompasses "a fragment"

of any size of SEQ ID NO: 2 having beta-glucosidase activity, Duvick et al discloses all claim limitations.

Remarks

No claim is allowed.

Contact information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

11/12/07

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